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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,425	01/23/2004	Deepa Eveleigh	5151	2018

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EXAMINER	
HUMPHREY, DAVID HAROLD	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,425	EVELEIGH ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Claims 1 and 4, link Inventions I and II. Claim 7 links Inventions III and IV. Claim 10 links Inventions IV and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, 4, 7, and 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2 and 5, drawn to a method for providing patient diagnosis or distinguishing between normal and disease tissues wherein the level of expression of one or more genes selected from the group consisting of SEQ ID NOs: 1-96 is determined, classified in class 435, subclass 6.

II. Claims 3 and 6, drawn to a method for providing patient diagnosis or distinguishing between normal and disease tissues wherein the level of expression of one or more polypeptides selected from the group consisting of SEQ ID NOs: 97-191 is determined, classified in class 435, subclass 7.1.

III. Claim 8, drawn to a method to monitor the response of a patient being treated for colon cancer by administering an anti-cancer agent and determining the level of expression of one or more genes selected from the group consisting of SEQ ID NOs: 1-96, classified in class 435, subclass 7.23.

IV. Claim 9, drawn to a method to monitor the response of a patient being treated for colon cancer by administering an anti-cancer agent and determining the level of expression of one or more polypeptides selected from the group consisting of SEQ ID NOs: 97-191, classified in class 424, subclass 9.2.

V. Claim 11, drawn to a method of identifying a compound useful for the treatment of colon cancer comprising comparing the expression levels of one or more genes selected from the group consisting of SEQ ID NOs: 1-96 prior to treatment with the compound and again after treatment with the compound, classified in class 435, subclass 330, for example.

VI. Claim 12, drawn to a method of identifying a compound useful for the treatment of colon cancer comprising comparing the expression levels of one or more polypeptides selected from the group consisting of SEQ ID NOs: 97-191 prior to treatment with the compound and again after treatment with the compound, classified in class 424, subclass 277, for example.

VII. Claim 13, drawn to an array for distinguishing between normal and disease tissues comprising two or more probes corresponding to two or more genes selected from the group consisting of SEQ ID NOs: 1-96, classified in class 536, subclass 23.1.

VIII. Claim 14, drawn to an array for distinguishing between normal and disease tissues comprising two or more probes corresponding to two or more polypeptides selected from the group consisting of SEQ ID NOs: 97-191, classified in class 530, subclass 300, for example.

NOTE: If group I or II is elected, claims 1 and 4 will be examined to the extent they read on the elected invention, a method of providing a patient diagnosis using *either* the genes *or* gene products, respectively. If group III or IV is elected, claim 7 will be examined to the extent it reads on the elected invention, a method of monitoring the response of a cancer patient to an anticancer agent using *either* the genes *or* gene products, respectively. If group V or VI is elected, claim 10 will be examined to the

extent it reads on the elected invention, a method of identifying a compound using *either* the genes *or* gene products, respectively.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions. The methods of Inventions I-VI involve different method steps and parameters and utilize patentably distinct reagents. For example, Invention I employs determining the level of expression of one or more genes from the group consisting of SEQ ID NOs: 1-96. However, Invention II requires determining the level of expression of one or more peptides from the group consisting of SEQ ID NOs: 97-191. Inventions III and IV contain an additional method step of administering an anti-cancer agent which is not required for methods I, II, V, or VI. Invention III utilizes administering an anti-cancer agent and then determining the level of expression of one or more genes from the group consisting of SEQ ID NOs: 1-96 whereas Invention IV administers an anti-cancer agent and measures the expression level of one or more peptides from SEQ ID NOs: 97-191. Inventions V and VI require a method step of administering a test compound which is not utilized in any of the other methods of Inventions I, II, III, or IV. Invention V is drawn to a method of screening compounds useful for colon cancer treatment comprising administering a test compound and determining the expression level of one or more genes from SEQ ID

NOs: 1-96. Invention VI requires administering a test compound and determining the expression level of one or more peptides from SEQ ID NOs: 97-191. Therefore, since these inventions utilize different reagents and method steps, they are patentably distinct.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions. Inventions VII and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention VII is drawn to an array consisting of two or more genes whereas Invention VIII is an array consisting of two or more polypeptides. Polypeptides and nucleic acids are made using different techniques and reagents and have materially different modes of operation in vivo. And while the nucleic acids may encode the polypeptides, proteins and nucleic acids have substantially different physical, chemical, structural and functional properties. DNA, deoxyribonucleic acids are unbranched polymers composed of four subunits but polypeptides are a linear order of amino acid residues. Therefore, the products of Inventions VII and VIII are patentably distinct.

Inventions VII and I, VII and III, VII and V, VIII and II, VIII and IV, VIII and VI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

806.05(h)). In the instant case, the nucleic acids of Group VII can also be used in hybridization assays to detect single nucleotide polymorphisms. The polypeptides of Group VIII can be used for determining antibody specificity and affinity.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

REQUIREMENT FOR FURTHER RESTRICTION

5. If Invention I, III, V, or VII, is elected, further restriction is required. Claims 2, 5, 8, 11, and 13, are drawn to composition claims reciting different combinations of individual nucleotide sequences. Applicant is required to select a particular specific combination of one or more sequences (not to exceed 10 sequences) from SEQ ID NOs: 1-96 for examination. **THIS IS NOT AN ELECTION OF SPECIES.**

The different sequences of SEQ ID NOs: 1-96 are patentably distinct because they are unique structures composed of different nucleic acid sequences. The search of any particular SEQ ID NO is not coextensive with the search of any other different SEQ ID NOEITHER one specific SEQ ID NO. OR one specific combination of SEQ ID NO and a reference against one sequence is not necessarily a reference against any other sequence.

6. If Invention II, IV, VI, or VIII, is elected, further restriction is required. Claims 3, 6, 9, 12, and 14, are drawn to composition claims reciting different combinations of individual polypeptide sequences. Applicant is required to select a particular specific combination of one or more sequences (not to exceed 10 sequences) from SEQ ID NOs: 97-191. **THIS IS NOT AN ELECTION OF SPECIES.**

The different sequences of SEQ ID NOs: 97-191 are patentably distinct because they are unique structures composed of different amino acid sequences. The search of any particular SEQ ID NO is not coextensive with the search of any other different SEQ ID NOEITHER one specific SEQ ID NO. OR one specific combination of SEQ ID NO

and a reference against one sequence is not necessarily a reference against any other sequence.

7. Applicant is advised that a reply to this requirement must include an identification of the elected Invention AND a specific combination of one or more SEQ ID NOs for examination.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

May 8, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER